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NASA Procedural Requirements

COMPLIANCE IS MANDATORY

NPR 8020.12C

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Subject: Planetary Protection Provisions for Robotic Extraterrestrial Missions

Responsible Office: Science Mission Directorate

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PARAMETER TITLE: Clean Room Requirement

VALUE	
UPPER	
ACCEPTABLE	Class 100,000/ISO Class 8
LOWER	

APPLICATION	
MISSION	
CATEGORY	III and IV
PLANET	All

PARAMETER DEFINITION: Procedures for spacecraft and payload assembly.

APPLICABLE SOURCE: Spacecraft and payloads.

CONSTRAINTS: All Category III and IV missions shall assemble and maintain spacecraft and payloads in Class 100,000 or ISO Class 8 clean rooms in the operational mode (Ref. 1, 2). The class is to be monitored and verified, with the sampling frequency and number of locations per a clean zone as specified in Ref. 1 or 2 for any flight hardware location within the clean room. Attendant controls and procedures must be similar to those employed by the Viking Project or Ref. 2. This requirement is independent of any other requirement, e.g., any bioburden limitation.

- REFERENCES:**
1. "Clean Room and Clean Work Station Requirements, Controlled Environments," Federal Standard No. 209E, 1992 (or latest revision).
 2. "Cleanrooms and associated controlled environments"
"Part 1: Classification of air cleanliness," ISO 14644-1, 1999.
"Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1," ISO 14644-2, 2000.
"Part 5: Cleanroom Operations," ISO 14644-5, 2004.

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PARAMETER TITLE: Average Encapsulated Microbial Density { $\bar{d}_v(0)$ }

VALUE		APPLICATION	
UPPER	130/cm ³	MISSION	All
ACCEPTABLE	130/cm ³	CATEGORY	III, IV
LOWER	130/cm ³	PLANET	All

PARAMETER DEFINITION: The average density of spores buried inside nonmetallic spacecraft material. This value reflects reductions experienced in the manufacture of the basic material but it does not account for any burden reduction during higher level assembly and test.

APPLICABLE SOURCE: Nonmetallic portions of the spacecraft.

CONSTRAINTS: If this parameter is used, it must be applied to the total volume of non-metallic material and further subdivisions using source-specific density values $\bar{d}_v(0)$ shall not be made.

This value was derived assuming the subsequent use of heat sterilization. If processes are proposed that do not include heat for a Category IV mission, the value must be reassessed to assure its applicability for the proposed usage. It may be used without restriction for Category III mission burden estimates.

REFERENCES: Planetary Quarantine Advisory Panel (PQAP) Review, September 28, 1971, Denver, Colorado.

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PARAMETER TITLE: Source Specific Encapsulated MicrobialDensity {d_v(0)}

VALUE		APPLICATION	
MISSION	Category	PLANET	Source
UPPER		All	
ACCEPTABLE	See Below	III, IV	
LOWER		All	

PARAMETER DEFINITION: The average number of spores buried inside the i^{th} subassembly or component of a spacecraft. The number can be expressed in terms of volume or area according to the application as specified below.

APPLICABLE SOURCE: Non-metallic materials on the spacecraft.

CONSTRAINTS: Source-specific density values can be used only if applied to the entire volume of spacecraft nonmetallic material without resorting to the average density value, $d_v(0)$, for any portion thereof. Values for this parameter must be derived for all applicable sources. Values are selected from the following categories and ranges depending upon the composition of, and manufacturing process for, each designated source:

Encapsulated organisms in:	$d_v(0)$
Electronic piece parts	3-150/cm ³
Other nonmetallic materials	1-30/cm ³
Enclosed surface densities:	
Clean room-highly controlled	0.05-0.5cm ²
Clean room-normal control	0.5-10/cm ²
Uncontrolled manufacturing	10-100/cm ²

In the use of this parameter, a rationale shall be presented for the selection of values less than the maximum of the applicable range specified. This value was derived assuming the subsequent use of heat sterilization. If processes are proposed that do not include heat for a Category IV mission, the value must be reassessed to assure its applicability for the proposed usage. It may be used without restriction for Category III mission burden estimates.

REFERENCES: PQAP Review, September 28, 1971, Denver, Colorado.

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PARAMETER TITLE: Surface Microbial Density ($d_s(0)$)

VALUE		APPLICATION	
MISSION	Category	PLANET	Category
UPPER		All	
ACCEPTABLE	See Below	III, IV	
LOWER		All	

PARAMETER DEFINITION: The average number of spores on any free surface (non-encapsulated) of a spacecraft system, subsystem, assembly or subassembly.

APPLICABLE SOURCE: All fallout burden on the spacecraft (exposed and mated).

CONSTRAINTS: Values of this parameter are selected from the following categories, depending on the manufacturing process and cleaning and contamination control procedures for the designated hardware:

Clean room 10^4 or better - highly controlled	$50/m^2$
Clean room 10^4 - normal control	$5 \times 10^2/m^2$
Clean room 10^5 - highly controlled	$1 \times 10^3/m^2$
Clean room 10^5 - normal control	$1 \times 10^4/m^2$
Uncontrolled manufacturing	$1 \times 10^5/m^2$

For estimating surface densities for vegetative microorganisms (for purposes other than to establish terminal sterilization cycles), multiply the above values by a factor of 10.

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PARAMETER TITLE: Temperature Dependence of D-Value (Z)

VALUE	
UPPER	21 C
ACCEPTABLE	21 C
LOWER	21 C

APPLICATION	
MISSION	All
CATEGORY	IV
PLANET	All

PARAMETER DEFINITION: The change in temperature which produces a factor of 10 change in a given D-value.

APPLICABLE SOURCE: All microbial burden subjected to dry heat sterilization cycles.

CONSTRAINTS: Applicable within the temperature range of 104 C to 125 C. Applicable to dry heat sterilization cycles meeting requirements of NPR 8020.12.

REFERENCES: 1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: D-Value for Microbial Spore Burden on Exposed Surfaces (D_{S125})

VALUE		APPLICATION	
UPPER	0.5 hr.	MISSION	All
ACCEPTABLE	0.5 hr.	CATEGORY	IV
LOWER	0.5 hr.	PLANET	All

PARAMETER DEFINITION: Time required to destroy 90 percent of the microbial spore population on surfaces subjected to sterilizing dry heat at a temperature of 125C at an absolute humidity corresponding to a relative humidity of less than 25 percent referenced to the standard conditions of 0 C and 760 torr.

APPLICABLE SOURCE: All microbial spore populations located on spacecraft "free" surfaces (i.e., such that gas exchange can take place).

CONSTRAINTS: Specified D-value can be applied where sterilization cycle conditions stated in NPR 8020.12C have been met. Thermal response of materials must be considered in design of sterilization cycles. Project must specify method for the measurement of these parameters and make allowances for stabilization times.

REFERENCES: 1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: D-Value for Microbial Spore Burden on Mated Surfaces (DM125)

VALUE		APPLICATION	
UPPER	1.0 hr.	MISSION	All
ACCEPTABLE	1.0 hr.	CATEGORY	IV
LOWER	1.0 hr.	PLANET	All

PARAMETER DEFINITION: Time required to destroy 90 percent of the microbial spore population on mated surfaces of spacecraft subjected to sterilizing dry heat at a temperature of 125 C at an absolute humidity corresponding to a relative humidity of less than 25 percent referenced to the standard conditions of 0 C and 760 torr.

APPLICABLE SOURCE: All spore populations on mated surfaces of spacecraft.

CONSTRAINTS: Specified D-value can be applied where sterilization cycle conditions stated in NPR 8020.12C have been met. Thermal response of materials must be considered in design of sterilization cycles. Project must specify method for the measurement of these parameters and make allowances for stabilization times.

REFERENCES: 1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: D-Value for Encapsulated Microbial Spore Burden (DB125)

VALUE		APPLICATION	
UPPER	5.0 hr.	MISSION	All
ACCEPTABLE	5.0 hr.	CATEGORY	IV
LOWER	5.0 hr.	PLANET	All

PARAMETER DEFINITION: Time required to destroy 90 percent of the microbial spore population encapsulated in nonmetallic spacecraft material subjected to sterilizing dry heat at a temperature of 125 C.

APPLICABLE SOURCE: All spore populations buried within non-metallic spacecraft materials.

CONSTRAINTS: Specified D-value can be applied where sterilization cycle conditions stated in NPR 8020.12C have been met. Thermal response of materials must be considered in design of sterilization cycles. Project must specify method for the measurement of these parameters and make allowances for stabilization times.

REFERENCES: 1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: Minimum Number of Spores per Assay (n_{min})

VALUE		APPLICATION	
UPPER		MISSION	All Requiring Terminal Sterilization
ACCEPTABLE	$\frac{1}{250}$	CATEGORY	IV
LOWER		PLANET	All

PARAMETER DEFINITION: The minimum number of spores per surface samples assayed acceptable in determining the minimum terminal sterilization cycle.

APPLICABLE SOURCE: All spacecraft surfaces.

CONSTRAINTS: The number of surface samples obtained per assay will be as specified in individual project microbiological assay plans per NPR 8020.12C. Typically, for spacecraft in the 50 - 500 m² range, there will be approximately 250 surface samples (each about 25 cm² in area) taken per assay. For this class of spacecraft, if all the surface samples used in the assay are negative, an assigned value shall be used for purposes of determining the minimum terminal sterilization cycle. This assigned value shall be one viable spore per total number of surface samples used in the assay.

REFERENCES: 1. Minutes of Meeting of Viking Terminal Sterilization Process, Martin Marietta Corporation, December 11, 1973, Denver, Colorado.

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PARAMETER TITLE: Fraction of Hardy Organisms and their Survival of Nominal Sterilization Cycles (N_H/N_0)

VALUE		APPLICATION	
UPPER	1×10^{-3}	MISSION	Any Requiring Sterilization
ACCEPTABLE	See Below	CATEGORY	IV
LOWER	1×10^{-4}	PLANET	All

PARAMETER DEFINITION: Hardy (heat resistant) organisms as a fraction of the total spore population on spacecraft surfaces. Survival of the hardy organisms is expressed as the ratio of the hardy organisms surviving a nominal sterilization cycle to the initial presterilization total spore population.

APPLICABLE SOURCE: All microbial spore populations located on spacecraft surfaces.

CONSTRAINTS: Hardy organisms comprise a fraction of 1×10^{-3} of the total spore population on spacecraft surfaces. For nominal sterilization cycles, i.e., 35-50 hours at temperatures of 111-125 C, the surviving fraction of hardy organisms is 1×10^{-4} . Therefore, in designing or assessing spacecraft sterilization cycles, the logarithmic death-rate model based on the D and Z values provided elsewhere in this specification book should not be used to predict lethality greater than 1×10^{-4} for microbial spore populations on spacecraft surfaces. The model is valid, however, for calculating lethality up to the level of the hardy surviving fraction, which, at 1×10^{-4} , establishes the maximum allowable lethality for the nominal sterilization cycles described above.

- REFERENCES:**
1. Thermal Resistance of Naturally Occurring Airborne Bacterial Spores. J.R. Puleo, et al., Planetary Quarantine Laboratory, Jet Propulsion Laboratory, 1978, Cape Canaveral, Florida.
 2. Statistics of the N_H/N_0 Ratio. Paper presented at the "Hardy" Organisms conference, Ames Research Center, November 1974, by P.D. Stabekis, Exotech Research & Analysis, Inc., Gaithersburg, Maryland.

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PARAMETER TITLE: Time-Temperature for Absolute Sterility (K ($\dagger T$))

VALUE		APPLICATION	
UPPER	$\geq 0.5 \text{ sec}$ $@ \geq 500 \text{ C}$	MISSION	All
ACCEPTABLE	Same	CATEGORY	All
LOWER	Same	PLANET	All

PARAMETER DEFINITION: The short time-high temperature conditions at which all organisms will be completely destroyed.

APPLICABLE SOURCE: Any source of terrestrial organisms associated with spacecraft hardware. Sources can be encapsulated, mated surface, open surface, or airborne. The temperature must exist at the location of the microbial burden for the required time duration.

CONSTRAINTS: Spacecraft organisms and their associated environment must reach a temperature of at least 500 C and must remain at this temperature for at least one half second. This specification was derived from high temperature sterilization tests of microbial contamination.

- REFERENCES:**
1. Hoffman, R. K., et al. Thermal Inactivation of Aerosolized *Bacillus subtilis* var. *niger* Spores. *Appl. Microbiol.* 22(4): Oct. 1971.
 2. Recommendations of PQAP, meeting held Feb. 1, 1973, New Orleans, Louisiana.

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PARAMETER TITLE: Probability of Surface Organisms Surviving Ultraviolet Radiation
(P (uv))



VALUE		APPLICATION	
UPPER	1	MISSION	All
ACCEPTABLE	See Below	CATEGORY	IV
LOWER	< 10^{-4}	PLANET	All

PARAMETER DEFINITION: Probability that a randomly selected organism exposed to extraterrestrial ultraviolet radiation will survive the dose applicable to the mission specific conditions.

APPLICABLE SOURCE: All organisms exposed to extraterrestrial ultraviolet radiation.

CONSTRAINTS: Selection of a particular value is to be made in two steps as follows:

1. Assuming complete exposure of the microorganisms, i.e., no shielding, P(uv) is determined by the function described below. The value of P(uv) as a function of time is a straight line on a log-log scale. For Martian missions, the line is defined by the following two points:
 - (a) $P(uv) = 1$ for a time of exposure of 1 minute, or less, and
 - (b) $P(uv) = 1 \times 10^{-4}$ for a time of exposure of 1 hour.
 P(uv) for times of exposure other than the above can be obtained by interpolation or extrapolation of these two points. For distances other than for Mars (1.5 AU.), the time of exposure needed shall be scaled by an inverse square relationship.
2. The value obtained in accordance with the above must be increased to allow for the effects of shielding by structures or by small particles such as dust and debris.

REFERENCES: PQAP Review on January 18-19, 1972 at Cape Canaveral, Florida.

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PARAMETER TITLE: Maximum Probability of Accidental Impact,
Category III (P_I , max (III))

VALUE	
UPPER	10^{-2}
ACCEPTABLE	10^{-2}
LOWER	10^{-2}

APPLICATION	
MISSION	Orbiter, Flyby
CATEGORY	III
PLANET	Mars

PARAMETER DEFINITION: The maximum allowable probability of accidental impact of a Category III mission.

APPLICABLE SOURCE: All Category III flyby and orbiter spacecraft and other associated hardware.

CONSTRAINTS: The project will conform to Class 100,000 contamination control . For a Category III orbiter, the value must not be exceeded for the period of orbital lifetime required. Launch vehicles must meet a 10^{-4} requirement.

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PARAMETER TITLE: Orbital Lifetime Probability, Mars

VALUE	
UPPER	See Below
ACCEPTABLE	See Below
LOWER	See Below

APPLICATION	
MISSION	Orbiter
CATEGORY	III
PLANET	Mars

PARAMETER DEFINITION: Maximum probability of impact of Mars by a Mars orbiter, or any subsystems thereof, over a specified orbital lifetime.

APPLICABLE SOURCE: Mars orbiters that do not meet the maximum total spore burden requirement (i.e., with total bioburden in excess of 5×10^5 spores).

CONSTRAINTS: Orbit characteristics shall be such that the $P_{I, \text{max}}$ (III) for the mission (10^{-7}) shall be met until twenty years from the launch of the mission. Between 20 and 50 years from launch, the spacecraft shall remain in orbit with an assurance ≥ 0.95 .

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PARAMETER TITLE: Maximum Total Microbial Spore Burden for Category III Missions to Mars

VALUE		APPLICATION	
UPPER		MISSION	Orbiter
ACCEPTABLE	$\leq 5.0 \times 10^5$ spores/vehicle	CATEGORY	III
LOWER		PLANET	Mars

PARAMETER DEFINITION: Maximum total spore burden for a Mars orbiter, including all subsystems thereof.

APPLICABLE SOURCE: Mars orbiters that do not meet the "Orbital Lifetime Probability Requirement, Mars."

CONSTRAINTS: The total microbial burden (i.e., spore burden on free surfaces, mated surfaces, and encapsulated in nonmetallic material) for each Category III orbiter shall be $\leq 5.0 \times 10^5$ spores, as measured by microbiological assay processes and techniques used for establishing the burden levels on the Viking landers and orbiters (Ref. 1), or other approved assay methods. It shall be incumbent on the project to demonstrate equivalence for techniques other than those used on Viking.

The microbial burden levels specified apply to spores on the orbiter system at launch. No allowance shall be made for burden reduction factors that may be associated with inflight or surface conditions on Mars (vacuum, UV, temperature, etc.)

This total microbial burden level (surface, mated, and encapsulated) is based on the average total presterilization microbial burden level for the Viking landers.

REFERENCES: 1. Viking '75 Program Microbiological Assay and Monitoring Plan, Viking '75 Project, M75-148-0.

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PARAMETER TITLE: Maximum Surface Microbial Spore Burden for Category IVa Missions to Mars

VALUE	
UPPER	
ACCEPTABLE	≤ 300 bacterial spores/m ² $\leq 3.0 \times 10^5$ bacterial spores/vehicle
LOWER	

APPLICATION	
MISSION	Lander, Probe
CATEGORY	IV
PLANET	Mars

PARAMETER DEFINITION: This specification establishes a maximum limit on the exposed surface bioburden for all Category IVa missions to Mars.

APPLICABLE SOURCE: Exposed exterior and interior spacecraft surfaces.

CONSTRAINTS: The surface bioburden for each Category IV probe or lander system, defined as all subsystems included in a single landing event, shall be an average of ≤ 300 bacterial spores per square meter and the total vehicle surface burden shall be $\leq 3.0 \times 10^5$ bacterial spores, as measured by microbiological assay processes and techniques used for establishing the burden levels on the Viking landers and orbiters (Ref. 1), or other approved assay methods. It shall be incumbent on the project to demonstrate equivalence for techniques other than those used on Viking.

The burden levels specified apply to organisms on the orbiter, probe, or lander system at launch. No allowance shall be made for burden reduction factors that may be associated with inflight or surface conditions on Mars (vacuum, UV, temperature, etc.).

These surface microbial burden levels are based on the average presterilization surface microbial burden levels for the Viking landers.

REFERENCES: 1. Viking '75 Program Microbiological Assay and Monitoring Plan, Viking '75 Project, M75-148-0.

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PARAMETER TITLE: Maximum Total Microbial Spore Burden for Category IV Missions to Mars

VALUE	
UPPER	
ACCEPTABLE	$\leq 5.0 \times 10^5$ bacterial spores/vehicle
LOWER	

APPLICATION	
MISSION	Lander, Probe
CATEGORY	IV
PLANET	Mars

PARAMETER DEFINITION: This specification establishes a maximum limit on the total spore burden for all Category IV missions to Mars.

APPLICABLE SOURCE: Mars landers and probes that have hardware making a planned hard landing and/or have a non-nominal impact requirement.

CONSTRAINTS: The total microbial burden (i.e., spore burden on free surfaces, mated surfaces, and encapsulated in non-metallic material) for each Category IV probe or lander system included in a single landing event, plus any cruise and entry vehicle hardware, shall be $\leq 5.0 \times 10^5$ bacterial spores, as measured by assay processes and techniques used for establishing the burden levels on the Viking landers (Ref. 1) or other approved methods.

The microbial burden levels specified apply to those subsystems which make a planned hard landing and/or have a non-nominal impact requirement. The 5.0×10^5 spores/vehicle includes the 3.0×10^5 spores/vehicle allocated to the exposed exterior and interior spacecraft surfaces.

The microbial burden levels specified apply to spores on the lander system at launch. No allowance shall be made for burden reduction factors that may be associated with inflight or surface conditions on Mars (vacuum, UV, temperature, etc.).

This total microbial burden level (surface, mated, and encapsulated) is based on the average total presterilization microbial burden level for the Viking landers. Applies to the presystem/subsystem sterilization cleanliness levels for IVb and IVc missions.

REFERENCES: 1. Viking '75 Program Microbiological Assay and Monitoring Plan, Viking '75 Project, M75-148-0.

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PARAMETER TITLE: Maximum Surface Microbial Spore Burden for Category IVb and IVc Missions to Mars

VALUE		APPLICATION	
UPPER		MISSION	Lander, Probe
ACCEPTABLE	≤ 30 bacterial spores on the free surfaces of a landed system	CATEGORY	IV
LOWER		PLANET	Mars

PARAMETER DEFINITION: This specification establishes a maximum limit on the free surface bioburden for all Category IVb and IVc missions to Mars.

APPLICABLE SOURCE: All free exterior and interior spacecraft surfaces.

CONSTRAINTS: The surface bioburden for each Category IVb probe or lander system, defined as all subsystems included in a single landing event, shall be ≤ 30 bacterial spores, as established by the application, to a lander meeting Category IVa specifications, of the dry heat microbial reduction process used for the Viking landers, and specified in this document. It shall be incumbent on the project to demonstrate equivalence for other sterilization/decontamination methods. Under special circumstances, this specification's applicability may be limited to selected subsystems for both Categories IVb and IVc.

The burden levels specified apply to organisms on the probe, or lander system at launch. No allowance shall be made for burden reduction factors that may be associated with inflight or surface conditions on Mars (vacuum, UV, temperature, etc.).

This surface microbial burden level is based on the estimated post-sterilization surface microbial burden level for the Viking landers.

REFERENCES: 1. Viking '75 Program Microbiological Assay and Monitoring Plan, Viking '75 Project, M75-148-0.

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PARAMETER TITLE: Maximum Probability of Contamination of an Europan Ocean

VALUE		APPLICATION	
UPPER		MISSION	All
ACCEPTABLE	$\leq 1.0 \times 10^{-4}$	CATEGORY	III and IV
LOWER		PLANET	Europa

PARAMETER DEFINITION: Maximum probability of contaminating an Europan ocean with terrestrial contamination.

APPLICABLE SOURCE: Europa flybys, orbiters, landers, and probes.

CONSTRAINTS: The probability of inadvertently contaminating an Europan ocean shall be less or equal to 1.0×10^{-4} per mission. The calculation of this probability should include a conservative estimate of poorly known parameters and address the following factors, at a minimum:

- (1) Microbial burden at launch.
- (2) Cruise survival for contaminating organisms.
- (3) Organism survival in the radiation environment adjacent to Europa.
- (4) Probability of landing on Europa.
- (5) The mechanisms of transport to the Europan subsurface.
- (6) Organism survival and proliferation before, during, and after subsurface transfer.

REFERENCES: 1. Space Studies Board, National Research Council, *Preventing the Forward Contamination of Europa*, National Academy Press, Washington, D.C., 2000]

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